IN THE UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

RECEIPT # _____
AMOUNT $ 250
SUMMONS ISSUED _____
LOCAL RULE 4.1 _____
WAIVER FORM _____
MCF ISSUED _____
BY DPTY. CLK. _____
DATE 5-5-05

COMMONWEALTH CARE ALLIANCE, HEALTH CARE FOR ALL, EMILY FEINBERG, individually and on behalf of persons similarly situated,

Plaintiffs,

v.

MERCK & CO., INC.,

Defendant.

CIVIL ACTION No. _____

05 - 10931 DPW

MAGISTRATE JUDGE _____

NOTICE OF REMOVAL OF DEFENDANT MERCK & CO., INC.

Defendant, Merck & Co., Inc. ("Merck"), through undersigned counsel, hereby removes the above-captioned action from the Suffolk Superior Court, Commonwealth of Massachusetts, to the United States District Court for Massachusetts, Eastern Division, pursuant to 28 U.S.C. §§ 1332, 1441, and 1446, and respectfully files this Notice of Removal and states:

1. This action involves allegations regarding the prescription drug VIOXX®. On February 16, 2005, the Judicial Panel on Multidistrict Litigation issued an order transferring 148 VIOXX® products liability cases to the United States District Court for the Eastern District of Louisiana (Fallon, J.) for coordinated pretrial proceedings under 28 U.S.C. § 1407. Merck intends to seek the transfer of this action to that Multidistrict Litigation, *In re VIOXX Products Liability Litigation,* MDL No. 1657, and will shortly provide the MDL Panel notice of this action pursuant to the "tag-along" procedure contained in the MDL Rules.

2. On or about February 17, 2005, Commonwealth Care Alliance, Health Care For All, and Emily Feinberg, individually and on behalf of persons similarly situated, commenced

this putative class action against Merck by filing a Class Action Complaint ("Complaint") in the Suffolk Superior Court, Commonwealth of Massachusetts, bearing Case No. 05-0644.

3. As more fully set out below, this case is properly removed to this Court pursuant to 28 U.S.C. § 1441 because Merck has satisfied the procedural requirements for removal and this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332.

I. MERCK HAS SATISFIED THE PROCEDURAL REQUIREMENTS FOR REMOVAL

4. Merck was served with a copy of Plaintiffs' Complaint on April 20, 2005. Accordingly, this Notice of Removal is timely filed pursuant to 28 U.S.C. § 1446(b).

5. The Suffolk Superior Court, Commonwealth of Massachusetts is located within the District of Massachusetts, Eastern Division. Therefore, venue is proper pursuant to 28 U.S.C. § 89(c) because the District Court for the District of Massachusetts is the "district and division embracing the place where such action is pending." *See* 28 U.S.C. § 1441(a).

6. No previous application has been made for the relief requested herein.

7. Merck is the only defendant in this action. Merck therefore need not obtain the consent of any party to remove this action.

8. Pursuant to 28 U.S.C. § 1446(a), a copy of all process, pleadings, and orders served upon the defendant, which papers include the summonses and complaints, is attached as Exhibit A. Pursuant to 28 U.S.C. § 1446(d), a copy of this Notice of Removal is being served upon counsel for plaintiffs and a copy is being filed with the Clerk of the Suffolk Superior Court, Commonwealth of Massachusetts.

II. REMOVAL IS PROPER BECAUSE THIS COURT HAS SUBJECT MATTER JURISDICTION PURSUANT TO 28 U.S.C. §§ 1332 AND 1441

9. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 because this is a civil action between citizens of different states in which the amount in controversy exceeds the sum of $75,000.

A. Complete Diversity Of Citizenship

10. There is complete diversity between Plaintiffs and Merck.

11. Plaintiff Commonwealth Care Alliance ("CCA") is "located in Boston, Massachusetts." (Compl. ¶ 14.) Accordingly, upon information and belief, Massachusetts is the state in which the Plaintiff CCA maintains its principal place of business and is incorporated; therefore, Massachusetts is the state of which the Plaintiff CCA is a citizen.[1]

12. The Plaintiffs' Complaint does not contain any mention of the Plaintiff Health Care For All ("HCFA") except in the case caption. Upon information and belief, HCFA is a non-profit organization with its principal place of business at 30 Winter Street, 10th Floor, Boston, MA 02108. *See* http://www.hcfama.org. Accordingly, upon information and belief, Massachusetts is the state in which the Plaintiff HCFA maintains its principal place of business and is organized; therefore, Massachusetts is the state of which the Plaintiff HCFA is a citizen.

13. Plaintiff Emily Feinberg is alleged to be a resident of the Commonwealth of Massachusetts. (Compl. ¶ 15.) Plaintiff Feinberg has not alleged residency in any other state.

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[1] Plaintiffs' Complaint alleges that CCA

> paid for Nexium on behalf of its beneficiaries during the Relevant Period, and was injured by the illegal conduct described in this Complaint. CCA has standing to bring this action on behalf of itself and all other payors who paid for Nexium in [sic] or purchased in the Commonwealth of Massachusetts.

Accordingly, upon information and belief, Massachusetts is the state in which the Plaintiff is domiciled and, therefore, the state of which the Plaintiff is a citizen.[2]

14. Merck is, and was at the time the Plaintiffs commenced this action, a corporation organized under the laws of the State of New Jersey with its principal place of business at One Merck Drive, White House Station, New Jersey, and therefore, is a citizen of New Jersey for purposes of determining diversity. 28 U.S.C. § 1332(c)(1).

B. The Amount In Controversy Requirement Is Satisfied

15. The Plaintiffs in this case allege that "[d]espite knowing that Vioxx posed serious cardiovascular risks, Merck made a business decision to downplay these risks and push Vioxx to market." (Compl. ¶ 42.) Based on these allegations, the Plaintiffs purport to represent a class of "[a]ll residents or entities in Massachusetts who purchased Vioxx in the four (4) years preceding the filing of th[e] Complaint up to and including the present." (Compl. ¶ 101.) The Plaintiffs allege that the putative class "consists of millions of individuals and entities throughout Arizona," though they presumably mean Massachusetts.[3] (Compl. ¶ 102.)

(Compl. ¶ 14.) Merck assumes that this is a typographical error because Nexium® is manufactured by AstraZeneca, not Merck & Co., Inc., and is not relevant to this action.

[2] The Plaintiffs also allege that

> Glenn Crenshaw purchased Vioxx and was injured by the illegal conduct described in this Complaint. Specifically, he took Nexium for approximately one year during which he paid co-payments through his insurance plan. As an individual, Glen Crenshaw pursues this class action on behalf of himself and all those similarly situated.

(Compl. ¶ 15.) Mr. Crenshaw is not named as a plaintiff in the caption for this action, nor do the Plaintiffs provide a basis for Merck to determine his citizenship for purposes of diversity jurisdiction. Additionally, as noted previously, Nexium® is manufactured by AstraZeneca, not Merck & Co., Inc., and cannot be relevant to this action. Therefore, Merck assumes that this is a typographical error.

[3] The Plaintiffs' Complaint also contains numerous other references to Arizona that seemingly have no connection to the Plaintiffs' stated claims and proposed class. (*See, e.g.*, ¶ 3 ("millions of citizens of Arizona have used [Vioxx]"); ¶ 5 ("millions of patients in Arizona who have already purchased and consumed Vioxx"); ¶ 12 ("worth

16. The Plaintiffs allege two separate claims for relief: violations of common law fraud and negligent misrepresentation (Count I), and restitution/unjust enrichment (Count II).[4] Based on these allegations, the Plaintiffs seek several forms of relief, including: appropriate damages, disgorgement, appropriate injunctive relief, attorneys' fees and "[a]ll other relief to which Plaintiff [sic] and members of the Class may be entitled at law or in equity." (Compl., Prayer for Relief at 28-29.)

13. The Plaintiffs' claims meet the jurisdictional threshold on several independent grounds.

14. First, the damages the Plaintiffs seek on an individual basis easily satisfy the amount in controversy. The Plaintiffs allege that they and the proposed class "have all been directly and proximately injured as the result of Defendant's wrongful conduct." (Compl. ¶ 112.) Accordingly, the Plaintiffs seek damages, injunctive relief, disgorgement, attorneys' fees and "[a]ll other relief to which Plaintiff and members of the Class may be entitled." (Compl., Prayer for Relief.) Together, these requests easily amount to at least $75,000. Assuming the various types of damages the Plaintiffs seek equal just $10,000 per person or entity, the Plaintiffs' inevitable request for punitive damages[5] would easily bring the total to $60,000 (*i.e.*,

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substantially less than the price paid by Arizona payors"); ¶ 13 ("in violation of the Arizona Consumer Fraud Act"); ¶ 16 ("Merck . . . conduct[s] business in Arizona")). Despite the Plaintiffs' frequent references to Arizona, they bring "this class action under the common law of Massachusetts" (Compl. ¶ 17) on behalf of "[a]ll residents or entities in Massachusetts who purchased Vioxx." (Compl. ¶ 101.) Therefore, for purposes of this Notice of Removal only, Merck assumes that the Plaintiffs' complaint is not intended to include residents of Arizona in the class definition and seeks leave of the Court to amend this Notice, if necessary.

[4] Near the beginning of their Complaint, the Plaintiffs allege that they "seek damages and restitution and/or disgorgement . . . pursuant to practices . . . in violation of the Arizona Consumer Fraud Act and the common law of unjust enrichment." (Compl. ¶ 13.) If this constitutes an additional claim against Merck under Chapter 93A of the *Massachusetts* General Laws, then it contributes to the amount in controversy, which exceeds $75,000 for each named plaintiff, as explained below.

[5] Massachusetts law allows recovery for punitive damages for intentional fraud. *See McEvoy Travel Bureau, Inc. v. Norton Co.*, 563 N.E.2d 188, 195 (Mass. 1990) ("an intentional fraud can constitute a basis for the multiplication of

five times the compensatory request), and a standard attorney fee of 30% would increase the amount in controversy to $78,000. The additional equitable relief they seek (even if divided among all proposed class members), would drive that figure even higher, amply satisfying the jurisdictional threshold.[6]

15. Second, given the nature of the Plaintiffs' claim that Merck sought to "conceal the drug's cardiovascular risks from both doctors and the public" (Compl. ¶ 48) and plaintiffs' request that the Court enter orders for "appropriate injunctive relief" and "[a]ll other relief to which Plaintiff and members of the Class may be entitled at law or in equity" (Compl., Prayer for Relief at 29), it is clear that they are seeking to lay the groundwork for a medical monitoring claim that will emerge once the time period for removal has expired. Indeed, the Plaintiffs' class description overlaps those of 19 nationwide VIOXX class actions in which the Plaintiffs explicitly seek medical monitoring, including one filed in this district. *See Saia v. Merck & Co.*, Inc., No. 04-12166 RCL (D. Mass. Oct. 14, 2004) (attached as Ex. B.).

16. As numerous federal courts have found in similar cases, a request for the creation of a medical monitoring fund satisfies the amount-in-controversy requirement because there are fixed costs to establishing such a fund — regardless of the number of class members. *See, e.g.*,

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damages"). The Plaintiffs appear to be alleging intentional fraud, with allegations that "Merck was well aware that the cardiovascular risks it sought to conceal were particularly relevant to consumers" (Compl. ¶ 49) and "Merck's internal marketing documents were specifically intended to prevent the dissemination of damaging information about Vioxx safety concerns." (Compl. ¶ 61.)

[6] There is conflicting authority in the First Circuit as to whether 28 U.S.C. § 1367 authorizes federal courts to exercise supplemental jurisdiction over the claims of absent class members. *See Ortega v. Star-Kist Foods, Inc.*, 370 F.3d 124, 132 n.6 (1st Cir. 2004) (noting the split authority in the First Circuit while expressing no opinion "regarding the application of § 1367 in class actions"). However, the majority of other circuits have found that supplemental jurisdiction is applicable to class actions, and the Supreme Court is expected to rule on this issue shortly. *Allapattah Servs., Inc. v. Exxon Corp.*, 333 F.3d 1248, 1254 (11th Cir. 2003), *cert. granted*, 160 L. Ed. 2d 221, 125 S. Ct. 317 (2004). Even if some of the proposed class members purport to assert claims for less than $75,000, this Court has jurisdiction over the remainder of the proposed class members' claims pursuant to 28 U.S.C. § 1367.

In re Diet Drugs, No. Civ. A. 98-20626, 1999 WL 673066, at *5 (E.D. Pa. Aug. 26, 1999) (holding that the value of a medical monitoring fund should be measured by the cost to the defendant); *In re Baycol Prods. Liab. Litig.*, MDL No. 1431, 2003 WL 22038708, at *3-*7 (D. Minn. Feb. 25, 2003) (holding that request for a medical monitoring fund met amount-in-controversy requirement); *Jackson v. Johnson & Johnson, Inc.*, No. 01-2113 DA, 2001 WL 34048067, at *5 (W.D. Tenn. Apr. 3, 2001) (same); *In re Rezulin Prod. Liab. Litig.*, 168 F. Supp. 2d 136, 152-53 (S.D.N.Y. 2001) (same).

17. Other courts have similarly held that the amount in controversy "is appropriately measurable as the cost to defendant of creating such a [medical monitoring] fund" and should not be divided among the plaintiffs because "the full amount of the research, rather than some fraction of it, must be funded to benefit any single member of the contemplated class." *Katz v. Warner-Lambert Co.*, 9 F. Supp. 2d 363, 364-65 (S.D.N.Y. 1998). *See also In re Rezulin Prods. Liab. Litig.*, 168 F. Supp. 2d 136, 153 (S.D.N.Y. 2001) (medical monitoring request met amount in controversy because costs of setting up fund would "include, among other things, claim forms, selection of and consultation with medical personnel, verification of expenses, data collection, record retention, call centers, training of administrative personnel, as well as development of computer programs," the cost of which would exceed $75,000); *In re Diet Drugs*, No. Civ. A. 98-20626, 1999 WL 673066, at *7 (E.D. Pa. Aug, 26, 1999) (federal diversity jurisdiction exists over phen-fen cases seeking medical monitoring); *Jackson v. Johnson & Johnson, Inc.*, No. 01-2113 DA, 2001 WL 34048067, at *5 (W.D. Tenn. Apr. 3, 2001) ("clerical and administrative costs of such a program alone would exceed $75,000"); *Holcombe v. Smithkline Beecham Corp.*,

272 F. Supp. 2d 792, 798 (E.D. Wis. 2003) ("[t]he defendant's cost is the cost of complying with an injunction in favor of a single plaintiff").

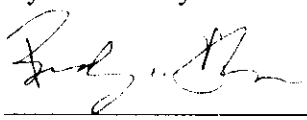
18. As set forth in the attached declaration from Dr. Merlin Wilson, the start-up administrative costs "for any medical monitoring regime" for VIOXX® users would exceed $75,000, given the large number of people who were prescribed VIOXX®, the "clerical staffing and computer systems" that would be necessary to "track patients and keep appropriate records," the "professional staffing from physicians and nurses" that would be necessary to ensure that a proper protocol is being followed, and the expense of establishing a "billing system to ensure that the members of the putative class are being reimbursed." (*See* Declaration of Merlin R. Wilson, M.D., F.A.C.P., F.A.C.R. (attached hereto as Exhibit C).) Thus, the request for injunctive relief alone puts more than $75,000 in controversy.

19. Third, the Plaintiffs seek "restitution and/or disgorgement of all unlawful or illegal profits received by [Merck]" (Compl., Prayer for Relief at 29) as a result of Merck's "unlawful and/or wrongful collection of . . . payments for Vioxx." (Compl. ¶ 116.) Plaintiffs allege sales of Vioxx® reached "$2.5 billion in 2003" alone. (Compl. ¶ 1.) In similar circumstances, courts have held that claims for disgorgement satisfy the amount-in-controversy requirement because unlike damages, they should be considered in the aggregate. *See Williams v. Purdue Pharma Co.*, No. 02-0556, 2003 U.S. Dist. LEXIS 19268, at *18 (D.D.C. Feb. 27, 2003) (aggregating disgorgement claim where plaintiff sought a "refund of all monies acquired"); *In re Microsoft Corp. Antitrust Litig.*, 127 F. Supp. 2d 702, 720-21 (D. Md. 2001) (in putative class action, aggregating disgorgement claims that were distinct from claims for damages); *In re Cardizem CD Antitrust Litig.*, 90 F. Supp. 2d 819, 826 (E.D. Mich. 1999) (same); *Aetna U.S. Healthcare, Inc. v. Hoechst Aktiengesellschaft*, 48 F. Supp. 2d 37, 40 (D.D.C.

1999) (same). The value of such disgorgement sought here would obviously exceed $75,000 and separately satisfy the jurisdictional minimum.

WHEREFORE, Defendant Merck respectfully removes this action from the Suffolk Superior Court, Commonwealth of Massachusetts bearing Case Number 05-0644 to this Court pursuant to 28 U.S.C. § 1441.

MERCK & CO., INC.
By its attorneys:



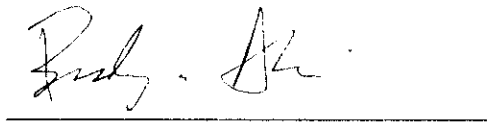
James J. Dillon (BBO# 124660)
Bradley E. Abruzzi (BBO# 651516)
FOLEY HOAG LLP
155 Seaport Boulevard
Boston, MA 02110-2600
(617) 832-1000

Dated: May 5, 2005

CERTIFICATE OF SERVICE

I certify that a true copy of the foregoing Notice of Removal was served on May 5, 2005 by regular U.S. mail, upon:

Thomas M. Sobol
HAGENS BERMAN SOBOL SHAPIRO LLP
One Main Street, 4th Floor
Cambridge, MA 02142
Counsel for Plaintiffs



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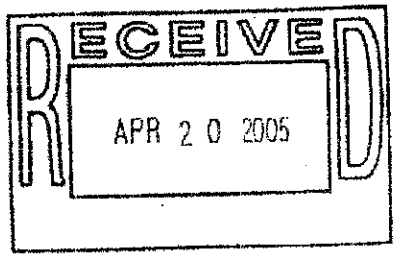
Service of Process Transmittal

04/19/2005
Log Number 510140827



TO: Debra A Bollwage
Merck & Co., Inc.
One Merck Drive
Whitehouse Station, NJ, 08889-0100

RE: **Process Served in Massachusetts**

FOR: Merck & Co., Inc. (Domestic State: NJ)

ENCLOSED ARE COPIES OF LEGAL PROCESS RECEIVED BY THE STATUTORY AGENT OF THE ABOVE COMPANY AS FOLLOWS:

TITLE OF ACTION:	Commonwealth Care Alliance, et. al., Pltfs. Vs Merck & Co., Inc., Dft.
DOCUMENT(S) SERVED:	Summons, Complaint
COURT/AGENCY:	Suffolk Superior Court, MA Case # 05-0844-BLS
NATURE OF ACTION:	Class Action - This action involves allegation of fraud, negligence and negligent misrepresentation on the part of defendants, the manufacturers and marketers of the prescription drug Vioxx.
ON WHOM PROCESS WAS SERVED:	C T Corporation System, Boston, MA
DATE AND HOUR OF SERVICE:	By Process Server on 04/19/2005 at 12:40
APPEARANCE OR ANSWER DUE:	Within 20 Days
ATTORNEY(S) / SENDER(S):	Thomas M. Sobol Hagens Berman Sobol Shapiro, LLP. One Main Street 4th Floor Cambridge, MA, 02142
ACTION ITEMS:	SOP Papers with Transmittal, via Fed Ex Priority Overnight, 790494419148
SIGNED: **PER:** **ADDRESS:**	C T Corporation System Dahriana Mitchell 101 Federal Street Boston, MA, 02110
TELEPHONE:	617-757-6403

Commonwealth of Massachusetts

SUFFOLK, ss.

SUPERIOR COURT DEPARTMENT
OF THE TRIAL COURT
CIVIL ACTION

No. 05-0644-BLS

Commonwealth Care Alliance, et al. , Plaintiff(s)

v.

Merck & Co., Inc. , Defendant(s)

SUMMONS

To the above-named Defendant: Merck & Co., Inc.

You are hereby summoned and required to serve upon Thomas M. Sobol of Hagens Berman Sobol Shapiro, LLP plaintiff's attorney, whose address is One Main Street, 4th Floor, Cambridge, MA 02142, an answer to the complaint which is herewith served upon you, within 20 days after service of this summons upon you, exclusive of the day of service. If you fail to do so, judgment by default will be taken against you for the relief demanded in the complaint. You are also required to file your answer to the complaint in the office of the Clerk of this court at Boston either before service upon plaintiff's attorney or within a reasonable time thereafter.

Unless otherwise provided by Rule 13(a), your answer must state as a counterclaim any claim which you may have against the plaintiff which arises out of the transaction or occurrence that is the subject matter of the plaintiff's claim or you will thereafter be barred from making such claim in any other action.

Witness, Barbara J. Rouse [redacted]o, Esquire, at Boston, the 19th day of April, in the year of our Lord two thousand and five.

Michael Joseph Donovan

Clerk/Magistrate

NOTICE TO DEFENDANT — You need not appear personally in court to answer the complaint, but if you claim to have a defense, either you or your attorney must serve a copy of your written answer within 20 days as specified herein and also file the original in the Clerk's Office.

NOTES.

1. This summons is issued pursuant to Rule 4 of the Massachusetts Rules of Civil Procedure.
2. When more than one defendant is involved, the names of all defendants should appear in the caption. If a separate summons is used for each defendant, each should be addressed to the particular defendant.
3. TO PLAINTIFF'S ATTORNEY: PLEASE CIRCLE TYPE OF ACTION INVOLVED

(1) TORT — (2) MOTOR VEHICLE TORT — (3) CONTRACT — (4) EQUITABLE RELIEF — (5) OTHER

FORM CIV.P. 1 3rd Rev.

CIVIL ACTION COVER SHEET	DOCKET NO.(S) B.L.S.	Trial Court of Massachusetts Superior Court Department County: SUFFOLK

PLAINTIFF(S)	DEFENDANT(S)
Commonwealth Care Alliance, Emily Feinberg and All Others Similarly Situated	Merck & Co., Inc.
ATTORNEY, FIRM NAME, ADDRESS AND TELEPHONE Thomas M. Sobol, Hagens Berman Sobol & Shapiro, One Main Street, Cambridge MA, 02142 BBO 471770 Board of Bar Overseers number:	ATTORNEY (if known)

Origin Code

Original Complaint

TYPE OF ACTION AND TRACK DESIGNATION (See reverse side)

CODE NO.	TYPE OF ACTION (specify)	TRACK	IS THIS A JURY CASE?
B12	unfair trade practices	*	(X) Yes ( ) No

The following is a full and detailed statement of the facts on which plaintiff relies to determine eligibility in to The Business Litigation Session.

This action involves allegations of fraud, negligence and negligent misrepresentations on the part of Defendants, the manufacturers and marketers of the prescription drug Vioxx. It involves complex issues related to the safety and efficacy of the drug Vioxx compared to other prescription medications in the same therapeutic category and issues related to the effects of the misleading marketing efforts of Defendants. In addition, it involves complex issues related to class certification.

***A Special Tracking Order shall be created by the Presiding Justice of the Business Litigation Session at the Rule 16 Conference.**

PLEASE IDENTIFY, BY CASE NUMBER, NAME AND COUNTY, ANY RELATED ACTION PENDING IN THE SUPERIOR COURT DEPARTMENT

"I hereby certify that I have complied with the requirements of Rule 5 of the Supreme Judicial Court Uniform Rules on Dispute Resolution (SJC Rule 1:18) requiring that I provide my clients with information about court-connected dispute resolution services and discuss with them the advantages and disadvantages of the various methods."

Signature of Attorney of Record _____ DATE: _____

AOTC-6 mtc005-11/99
A.O.S.C. 1-2000

COMMONWEALTH OF MASSACHUSETTS 05-0644 B Lo

SUFFOLK, ss. SUPERIOR COURT
TRIAL COURT DEPARTMENT

COMMONWEALTH CARE ALLIANCE, HEALTH CARE FOR ALL, EMILY FEINBERG, individually and on behalf of persons similarly situated, Plaintiffs v. MERCK & CO., INC. Defendants.	Civil Action No. SUFFOLK SUPERIOR COURT CIVIL CLERK'S OFFICE 2005 FEB 17 P 4:51 MICHAEL JOSEPH DONOVAN CLERK/MAGISTRATE

CLASS ACTION COMPLAINT AND JURY TRIAL DEMAND

Plaintiff, by and through counsel undersigned alleges upon personal knowledge as to himself and his own acts, and upon information and belief (based on the investigation of counsel) as to all other matters, as to which allegations she believes substantial evidentiary support will exist after reasonable opportunity for further investigation and discovery as follows:

I. NATURE OF THE ACTION

1. Merck & Co., Inc. ("Merck") received FDA approval in 1999 for Vioxx (rofecoxib), a prescription COX-2 selective, non-steroidal anti-inflammatory drug (NSAID), or painkiller, for the relief of the signs and symptoms of osteoarthritis, for the management of acute pain in adults, and for the treatment of menstrual symptoms. It was later approved for the relief of the signs and symptoms of rheumatoid arthritis in adults and children. More than 20 million Americans have taken Vioxx, and sales reached

$2.5 billion in 2003. Vioxx was at all times substantially more expensive than the existing pain relievers.

2. After receiving FDA approval Merck engaged in a massive sales and promotional campaign that was directed at doctors and consumers. Merck's sales force blitzed doctors' offices with literature and verbal presentations designed to convince both doctors and consumers that Vioxx was a superior drug for treatment of osteoarthritis, acute pain in adults, painful menstrual cycles and other types of disease. It portrayed Vioxx as "excellent news" for patients with stomach problems. Merck aggressively promoted Vioxx as an improvement over other NSAIDs, like naproxen and ibuprofen, because it had a lower risk of side effects such as gastrointestinal ulcers and bleeding. Merck did not promote or provide any balanced presentation as to Vioxx as having an unacceptably high risk of other side effects, such as heart attack and stroke. But internal emails confirm that Merck executives knew that Vioxx had an adverse cardiovascular profile, the risk was "clearly there." And Merck's marketing literature included a document intended for its sales representatives that discussed how to evade safety questions about Vioxx, labeled "Dodge Ball Vioxx."[1] Five years of profits later, the truth has come out.

3. Merck's campaign was a tremendous success. Vioxx became a household name and a blockbuster drug, millions of citizens in the State of Arizona have used it.

4. On September 30, 2004, the Center for Drug Evaluation and Research of the Food and Drug Administration issued a Memorandum concluding that Vioxx has adverse cardiovascular effects, which were evident as early as the 2000 VIGOR study: "Rofecoxib increases the risk of serious coronary heart disease defined as acute myocardial infarction and sudden cardiac death....The observation of an increased risk was first noted with the VIGOR trial, where a 5-fold difference in risk was found

[1] Richard Horton, THE LANCET, *Vioxx, The Implosion of Merck, and Aftershocks at the FDA* (Nov. 5, 2004).

between high-dose rofecoxib and naproxen. ***The manufacturer attributed this difference to a never before recognized protective effect of naproxen.*** To explain a 5-fold difference, naproxen would have had to be one of the most potent and effective cardio-protectants known. Three cohort studies and the present nested case-control study found no evidence of cardio-protection with naproxen. The three case-control studies that reported a protective effect were misleading. When analyzed in a manner comparable to the present study, ***no protective effect is shown.***"[2]

5. On the same day, September 30, 2004, Merck issued a press release announcing the withdrawal of Vioxx based on "new" data indicating an increased risk of cardiovascular events, such as heart attack and stroke.[3] Merck agreed to reimburse patients for Vioxx purchased but not used as of September 30, 2004. This does nothing, however, for the millions of patients in Arizona who have already purchased and consumed Vioxx and who paid more than they would have or should have because it was advertised as a premium drug with reduced side effects and/or who would not have purchased Vioxx in the first place had they know about its adverse cardiovascular effects. If Merck had told the truth from the outset, assuming that Vioxx would have even been viable, it would not have been billed as a premium drug with a cost that was much higher than alternative pain relievers. Naproxen retails for about $0.06 per pill or $6.00 per bottle. Vioxx, before it was withdrawn from the market sold for up to $3.00 per pill, or $300 per bottle.

6. When Merck & Co. pulled its big-selling painkiller Vioxx off the market in September, Chief Executive Raymond Gilmartin said the company was "really putting

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[2] David J. Graham, MD, MPH, Associate Director for Science, Office of Drug Safety, Center for Drug Evaluation and Research, FDA, *Risk of Acute Myocardial Infarction and Sudden Cardiac Death in Patients Treated with COX-2 Selective and Non-selective NSAIDs* 13 (Sept. 30, 2004).

[3] Merck, *Merck Announces Voluntary Withdrawal of VIOXX*, available at http://www.vioxx.com/vioxx/documents/english/vioxx_press_release.pdf (accessed Nov. 5, 2004).

patient safety first." He said the study findings prompting the withdrawal, which tied Vioxx to heart-attack and stroke risk, were "unexpected."

7. But internal Merck e-mails and marketing materials as well as statements made by outside scientists show that the company fought forcefully for years to keep safety concerns from destroying the drug's commercial prospects, thus enabling it to sell Vioxx as a premium drug when it was not.

8. Merck's first worry, in the mid-to-late 1990s, was that its drug would show greater heart risk than cheaper painkillers that were harsh on the stomach but were believed to reduce the risk of heart attacks. Several company officials discussed in e-mails how to design a study that would minimize the unflattering comparison, even while admitting to themselves that it would be difficult to conceal.

9. By 2000, one e-mail suggests Merck recognized that Vioxx didn't merely lack the protective features of old painkillers but that something about the drug itself was linked to an increased heart risk. On March 9, 2000, the company's powerful research chief, Edward Scolnick, e-mailed colleagues that the cardiovascular events "are clearly there" and called it a "shame." He compared Vioxx to other drugs with known side effects and wrote, "there is always a hazard." But the company's public statements after Dr. Scolnick's e-mail continued to reject the link between Vioxx and increased intrinsic risk.

10. As academic researchers increasingly raised questions about Vioxx's heart safety, the company struck back hard. It even sued one Spanish pharmacologist, trying unsuccessfully to force a correction of an article he wrote. In another case, it warned that a Stanford University researcher would "flame out" unless he stopped giving "anti-Merck" lectures, according to a letter of complaint written to Merck by a Stanford professor. A company training document listed potential tough questions about Vioxx and said in capital letters, "DODGE!" Dodge was a good nickname for Merck's strategy

and its deceptive conduct allowed it to market Vioxx at a premium price, forcing businesses to pay far in excess of what they should have.

11. As detailed herein, Merck successfully dodged the meaningful revelation of adverse facts about Vioxx until September 30, 2004.

12. On November 5, 2004, the influential British Medical Journal published an analysis of all the clinical trials of Vioxx completed June 2001 and concluded that "our findings indicate that Rofecoxib should have been withdrawn several years earlier." If Merck had made proper disclosures, the drug Vioxx would have been withdrawn, not marketed and/or worth substantially less than the price paid by Arizona payors.

13. In this action, Plaintiffs seek damages and restitution and/or disgorgement arising out of Merck's sale and promotion of Vioxx pursuant to practices and acts that are unfair, false, fraudulent, deceptive and unlawful in violation of the Arizona Consumer Fraud Act, A.R.S. § 44-1522 ("CFA") and the common law of unjust enrichment.

II. PARTIES

14. Plaintiff Commonwealth Care Alliance ("CCA") is a prepaid care system contracting with Medicare and Massachusetts Medicaid to provide comprehensive care to vulnerable, high cost populations. It is located in Boston, Massachusetts. CCA is third-party payor that paid for Nexium on behalf of its beneficiaries during the Relevant Period, and was injured by the illegal conduct described in this Complaint. CCA has standing to bring this action on behalf of itself and all other third-party payors who paid for Nexium in or purchased in the Commonwealth of Massachusetts.

15. Plaintiff Emily Feinberg is a resident of the Commonwealth of Massachusetts residing in Jaimaea Plain, Massachusetts. During the Relevant Period, Glenn Crenshaw purchased Vioxx and was injured by the illegal conduct described in this Complaint. Specifically, he took Nexium for approximately one year during which

he paid co-payments through his insurance plan. As an individual, Glenn Crenshaw pursues this class action on behalf of himself and all those similarly situated.

16. Defendant Merck & Co., Inc. ("Merck") is a New Jersey corporation conducting business in the State of Arizona.

III. JURISDICTION AND VENUE

17. Plaintiffs bring this class action under the common law of Massachusetts.

18. This Court has subject matter jurisdiction over all causes of action asserted herein pursuant to Mass. Gen. Laws ch. 212 § 4. This Court has personal jurisdiction over the parties because Plaintiffs and the members of the Class submit to the jurisdiction of this Court and Defendants systematically and continually conduct business in, or otherwise intentionally avails itself of, the Massachusetts marketplace through the production, promotion, sale, marketing and distribution of its products and services in Massachusetts. Mass. Gen. Laws ch. 223A § 3.

19. Venue is proper in this Court because Plaintiffs reside in Suffolk County and Defendants conduct business in Suffolk, including marketing, advertising and sales directed at Massachusetts residents, and maintain their agent for service of process in Suffolk County. Mass. Gen. Laws ch. 223 § 1.

IV. FACTUAL ALLEGATIONS

A. Medical/Scientific Background Concerning Selective COX-2 Inhibition and Cardiovascular Risks

20. At issue in this case is the prescription drug Vioxx. Vioxx belongs to the class of pain medications called non-steroidal anti-inflammatory drugs ("NSAIDs"). Aspirin and ibuprofen are examples of well-known NSAIDs.

21. NSAIDs reduce pain by blocking the body's production of pain transmission enzymes called cyclooxygenase or "COX." There are two types of COX enzymes, COX-1 and COX-2.

22. In addition to transmitting pain sensations, COX-1 is involved in maintaining and repairing gastrointestinal tissue.

23. It is generally accepted in the medical community that blocking the COX-1 enzyme hampers the body's ability to repair gastric tissue and causes harmful gastrointestinal side-effects, including stomach ulceration and bleeding.

24. In addition to transmitting pain sensations, COX-2 is involved in the production of prostacyclin, a substance responsible for preventing the formation of blood clots.

25. It is generally accepted in the medical community that blocking the COX-2 enzyme encourages the formation of blood clots and causes various clot-related cardiovascular events, including: heart attack, stroke, unstable angina, cardiac clotting and hypertension.

26. Traditional NSAIDs, like aspirin, reduce pain sensations by inhibiting both COX-1 and COX-2 enzymes. As would be expected, traditional NSAIDs cause gastrointestinal ulcers. However, because of a complex chemical balance in the human body, traditional NSAIDs do not cause blood clots, but actually reduce the risk of clots and help to protect heart function.

27. For decades, in the absence of other treatment options, consumers seeking pain relief were forced to accept and live with the gastrointestinal risks of traditional NSAIDs. Many consumers without gastrointestinal problems also became accustomed to taking an "aspirin a day" to benefit from its cardio-protective effects.

28. Merck set out to develop a "selective" drug that would block only the COX-2 enzyme, thus supposedly allowing the proper maintenance of gastric tissue while still reducing pain sensations.

29. In the late 1990s Merck was facing the loss of patent protection on several top drugs and needed a big hit. However, it would be difficult to penetrate the mass

market if doctors and patients believed that by choosing Vioxx, they were forgoing a potential heart benefit.

B. Early On Merck Is Aware of Dangers of Vioxx

30. A November 21, 1996, memo by a Merck official shows the company wrestling with this issue. It wanted to conduct a trial to prove Vioxx was gentler on the stomach than older painkillers. But to show the difference most clearly, the Vioxx patients couldn't take any aspirin. In such a trial, "there is a substantial chance that significantly higher rates" of cardiovascular problems would be seen in the Vioxx group, the memo said.

31. A similar view was expressed in a February 25, 1997, e-mail by a Merck official, Briggs Morrison. He argued that unless patients in the Vioxx group also got aspirin, "you will get more thrombotic events" – that is, blood clots – "and kill [the] drug."

32. In response, Alise Reicin, now a Merck vice president for clinical research, said in an e-mail that the company was in a "no-win situation." Giving study subjects both Vioxx and aspirin, she wrote, could increase the "relative risk," apparently referring to gastrointestinal problems. But, she added, "the possibility of increased CV [cardiovascular] events is of great concern." From the context, it seems Dr. Reicin meant "increased" relative to older drugs.

33. She added in parentheses: "I just can't wait to be the one to present those results to senior management!" She proposed that people with high risk of cardiovascular problems be kept out of the study so the difference in the rate of cardiovascular problems between the Vioxx patients and the others "would not be evident."

C. The Vigor Trial

34. By 1996, Merck had developed a selective COX-2 inhibitor called MK-966 (later known as Vioxx) and announced its initiation of clinical trials.

35. In late 1996, Merck began to plan a large-scale, long-term, double-blind study of gastrointestinal toxicity in patients taking Vioxx or naproxen to treat arthritis. This study came to be called the Vioxx Gastrointestinal Outcomes Research study ("VIGOR").

36. On November 21, 1996, a Merck memo discussing the design of the VIGOR trial suggested that participants be permitted to use aspirin during the study to mute the cardiovascular risks of Vioxx: "there is a substantial chance that significantly higher rates" of cardiovascular problems would be seen in the Vioxx group.

37. On February 25, 1997, Merck employee Briggs Morrison sent an e-mail about the design of the VIGOR trial. Morrison suggested that VIGOR participants be allowed to take aspirin to avoid disclosing the cardiovascular risks of Vioxx: unless patients in the Vioxx group could take aspirin, he warned, "you will get more thrombotic events and kill [the] drug." A response to this e-mail from Alise Reicin, now a Merck vice president for clinical research, proposed that people at high risk of cardiovascular problems be excluded from the study so that the rate of cardiovascular problems in those participants taking Vioxx "would not be evident."

38. In designing VIGOR, Merck obviously had significant concerns about how to conceal the expected manifestation of cardiovascular risks posed by Vioxx. Merck ultimately designed VIGOR to produce the absolute minimum number of cardiovascular events, both by excluding patients with known heart problems from the study and by allowing participants to take aspirin during the study. In the event cardiovascular events occurred among the study population, Merck designed the reporting system to record them.

39. The VIGOR trial concluded in October 1998. After reviewing the VIGOR results, Merck knew that, despite its precautions against cardiovascular events, patients taking Vioxx suffered more than *twice* the number of adverse cardiovascular events and

five times the number of heart attacks as patients taking naproxen. Merck's scientists understood that the difference in cardiovascular events was so great that it could not have come solely from naproxen's protective effect, but that it had to involve some sort of risk inherent to Vioxx.

40. On March 9, 2000, Merck's research chief Edward Skolnick e-mailed his colleagues that the cardiovascular results seen in VIGOR "are clearly there." Dr. Sklonick also wrote that Vioxx was to blame: "[the cardiovascular result] is mechanism based as we worried it was."

41. Thus, by the time the VIGOR trial had ended, Merck knew that Vioxx posed serious cardiovascular risks, including heart attack, stroke, unstable angina, cardiac clotting and hypertension, for anyone who took it, and presented a specific additional threat to anyone with existing heart disease or cardiovascular risk factors.

42. Despite knowing that Vioxx posed serious cardiovascular risks, Merck made a business decision to downplay these risks and push Vioxx to market on claimed improvements in gastrointestinal safety. This decision was made, in part, based on the fact that it would have been difficult for Vioxx to penetrate the mass market (and reap mass market sales) if doctors and patients knew that, by choosing Vioxx, they were exposing themselves to cardiovascular risks or foregoing the heart benefit offered by traditional NSAIDs.

43. From 1996 through 1998, Merck issued dozens of public statements that touted the efficacy and gastrointestinal safety of Vioxx. Not one of these statements mentioned cardiovascular safety issues or revealed any "mechanism based" problems with Vioxx. To the contrary, Merck repeatedly rejected any link between Vioxx and increased cardiovascular risk and actually claimed that clinical results with Vioxx were consistent with the clot-preventing effects of naproxen.

44. On November 23, 1998, Merck submitted a New Drug Application for Vioxx to the U.S. Food and Drug Administration. The FDA granted expedited review of Merck's Vioxx submission by its Arthritis Drugs Advisory Committee ("the Committee").

45. The Committee reviewed the VIGOR gastrointestinal safety results, but did not touch on any cardiovascular safety issues. The reason for this was simple: Merck was not seeking any marketing approvals related to cardiovascular safety and had not yet published the VIGOR cardiovascular results.

46. On April 20, 1999, the Committee recommended to approve Vioxx for the treatment of osteoarthritis and acute pain but, in light of Merck's failure to substantiate claims of gastrointestinal superiority, that its package insert bear the same gastrointestinal warnings as traditional NSAIDs.

47. On May 21, 1999, the FDA accepted the Committee's recommendations and granted marketing approval for Vioxx.

48. In order to maximize its profits from the sale of Vioxx, Merck made a "business decision" to conceal the drug's cardiovascular risks from both doctors and the public. Merck intended to conceal this information by, among other things, initiating a marketing campaign that uniformly omitted to disclose cardiovascular safety risks, issuing repeated public denials of Vioxx cardiovascular risks, concealing information about the cardiovascular risks of Vioxx from doctors and consumers and refusing to fund independent studies of Vioxx cardiovascular safety.

49. Merck was well aware that the cardiovascular risks it sought to conceal were particularly relevant to consumers who use prescription arthritis pain relievers. Merck also knew that publicizing the cardiovascular risks associated with Vioxx would cut into its projected profits by reducing the number of people for whom Vioxx could be

prescribed, making the drug generally less attractive to doctors and patients, and necessitating a significant reduction in per tablet price.

50. In March 2000, the results of Vigor came in. They showed that Vioxx patients suffered fewer stomach problems than the naproxen group, but significantly more blood-clot-related problems – precisely the sort of result anticipated in the 1996-97 internal documents. The heart-attack rate in the Vioxx group appeared to be four times as high as the naproxen group. (Later analysis would show it to be five times as high.)

51. The difference was so wide that Dr. Scolnick, the Merck research chief, appeared to recognize it couldn't come solely from naproxen's protective effect but must involve some sort of risk inherent in Vioxx. In a March 9, 2000, e-mail with the subject line "Vigor," Dr. Scolnick said the results showed that the cardiovascular events "are clearly there." In an apparent acknowledgment that Vioxx's own mechanism was at least partially at fault for the heart data, he wrote: "it is a shame but it is a low incidence and it is mechanism based as we worried it was."

52. Dr. Scolnick wrote that he wanted other data available before the results were presented publicly, so "it is clear to the world that this" was an effect of the entire Cox-2 class, not just Vioxx. The research chief, by then nearing retirement after 15 years in his post, then recalled some of his greatest hits that also had side effects but were big sellers. In Vioxx, he wrote, "We have a great drug and like angioedema with vasotec and seizures with primaxin and myopathy with mevacor there is always a hazard. The class will do well and so will we." Dr. Scolnick didn't respond to phone messages seeking comment.

53. But in a news release that month, Merck offered no hint of Dr. Scolnick's suggestion that there was a "mechanism-based" problem with Vioxx or a "hazard" that went beyond Vioxx's failure to offer the protective benefits of other painkillers. Merck

said the Vigor trial results were "consistent with" naproxen's favorable effects, implying that this could explain why Vioxx didn't do as well.

54. The next month Merck issued another news release headlined, "Merck confirms favorable cardiovascular safety profile of Vioxx." While acknowledging the Vigor results, it said other trials and data had shown "NO DIFFERENCE in the incidence of cardiovascular events" between Vioxx and a placebo or between Vioxx and older painkillers.

D. Merck Developed a Uniform Marketing Strategy to Conceal the Cardiovascular Risks of Vioxx Risks From Doctors and Consumers

55. Even before it received FDA approval to market Vioxx, Merck engaged in an intensive pre-release marketing campaign to bolster consumer interest and orders.

56. Merck's pre-release marketing campaign conveyed the uniform message that Vioxx provided safe and effective pain relief while omitting any mention of cardiovascular risks.

57. Merck's pre-release marketing campaign showed positive results. Sales projections for Vioxx based on early orders and inquiries surpassed $2 billion per year. ***Merck based this calculation on a proposed wholesale price of $2.02 per tablet □ about one hundred times the cost of a generic aspirin.***

58. In June 1999, Merck released Vioxx for sale in the U.S. This release was accompanied by the largest direct-to-consumer marketing campaign in history. Merck's Vioxx uniform marketing message was that Vioxx provided safe and effective pain relief, while omitting any mention of cardiovascular risk.

59. Merck spent more than $161 million on direct-to-consumer marketing in 2000 alone to disseminate this message, and more than $100 million in each of the following four years.

60. From its first day of release, Vioxx sales were aided by Merck's huge marketing budget and sophisticated marketing plans, by the fact that Merck had an entire staff devoted to putting a positive spin on even the most damaging disclosures and had managed to delay release of the cardiovascular results of the VIGOR trial.

61. Merck's internal marketing documents were specifically intended to prevent the dissemination of damaging information about Vioxx safety concerns. For example, one Merck memo addressed to "all field personnel with responsibility for Vioxx," provided an "obstacle handling guide" for Vioxx questions. If a doctor expressed concerns that Vioxx might increase the risk of a heart attack, he was to be given the oblique answer that the drug "would not be expected to demonstrate reductions" in heart attacks or other cardiovascular problems and that it was "not a substitute for aspirin."

62. Another Merck training document, entitled "Dodge Ball Vioxx," listed a series of questions doctors might ask about Vioxx. Among these statements are, "I am concerned about the cardiovascular effects of Vioxx" and "the competition has been in my office telling me that the incidence of heart attacks is greater with Vioxx than with Celebrex." Merck's instructions to be followed in responding to these questions consist of a single word: "DODGE!"

63. In April 2000, Merck responded to early news reports that Vioxx posed serious cardiovascular risks by simply denying that any such risks existed: "Extensive review of data from the completed osteoarthritis trials and on-going clinical trials with Vioxx ... have shown *no difference* in the incidence of cardiovascular events, such as heart attack, among patients taking Vioxx..." (emphasis in original).

64. In October 2000, Merck sent its long-overdue cardiovascular data from the VIGOR trial to the FDA for review. This was the first time that Merck had made the cardiovascular data gathered during VIGOR available to anyone without ties to Merck.

65. In November 2000, Merck published the results of its VIGOR trial in the New England Journal of Medicine. The article, written by Merck employees and by academics who received consulting contracts and research grants from Merck, made a vague reference to cardiovascular incidents but, astonishingly, did not fully report on the statistical incidence of cardiovascular complications seen in the study.

66. In February 2001, a full 19 months after Vioxx went on the market, the FDA published a Memorandum on the Vioxx cardiovascular safety data gathered during VIGOR. In this Memorandum, the FDA concluded that there "is an increased risk of cardiovascular thrombotic events, particularly [heart attack], in the [Vioxx] group compared with the naproxen group." The FDA considered and rejected each of the defenses raised by Merck to explain the statistically significant increase of cardiovascular incidents among Vioxx users.

67. Merck immediately responded to the FDA's Memorandum with a press release announcing its confidence "that the data presented today supports the excellent safety profile of Vioxx" and that "in the completed osteoarthritis trials and on-going clinical trials with Vioxx... there was no difference in the incidence of cardiovascular events, such as heart attacks among patients taking Vioxx, other NSAIDs and placebo" (emphasis in original).

68. In February 2001, the FDA also concluded that Merck should have to add a cardiovascular warning to its Vioxx packaging: "it would be difficult to imagine inclusion of VIGOR results in the [Vioxx] labeling without mentioning cardiovascular safety results in the study description as well as the Warnings sections."

69. Merck responded immediately with a press release stating its confidence "that the data presented today support the excellent safety profile of Vioxx." Merck's press release directly contradicted the FDA's findings by claiming, as it had before release of the VIGOR cardiovascular data, that "there was no difference in cardiovascular

mortality between the groups treated with Vioxx or naproxen... [and] no difference in the incidence of cardiovascular events, such as heart attacks, among patients taking Vioxx..." (emphasis in original).

70. Behind closed doors, Merck entered into negotiations with the FDA concerning the warning language to be used in its Vioxx labeling. These negotiations went on for another fourteen months while doctors and consumers continued to wait for work on the cardiovascular risks of a drug used by millions.

71. On May 22, 2001, Merck issued the first of a relentless series of publications touting the "favorable cardiovascular safety profile of Vioxx." In this release, disregarding the results of its own trial and the FDA's review, Merck stated "that there was no difference in cardiovascular mortality between the groups treated with Vioxx or naproxen... [and] *no difference* in the incidence of cardiovascular events, such as heart attacks, among patients taking Vioxx..." (emphasis in original).

72. These statements were repeated in countless continuing medical education symposiums and complimented by numerous papers in peer-reviewed medical literature by Merck employees and consultants, all of which attempted to debunk concerns about the adverse cardiovascular effects of Vioxx.

73. On August 21, 2001, independent doctors from the Cleveland Clinic performed their own meta-analysis of Vioxx trials on the issue of cardiovascular safety. Their conclusion was that Vioxx posed an increased risk of adverse cardiovascular events compared to naproxen. These doctors, concerned more with the increased number of heart attacks experienced by patients taking selective COX-2 inhibitors than with maximizing Merck's profits, urged Merck to conduct further trials to quantify the specific cardiovascular risks of Vioxx.

74. In response to the Cleveland Clinic article, Merck issued a press release touting "the overall and cardiovascular safety profile ... of Vioxx" and flatly denying the

existence of any cardiovascular safety issues: "there is no increase in the risk of cardiovascular events as a result of treatment with Vioxx."

75. Merck also asked the Cleveland Clinic Journal to run a rebuttal to this article, enforcing the cardiovascular safety profile of Vioxx. When it refused, Merck sent "Dear Doctor" letters to thousands of physicians nationwide that "strongly supported the cardiovascular safety profile" of Vioxx. Merck also sent "Dear Patient" letters to thousands of consumers nationwide identified from a prescription database that specifically minimized the risk of "heart attacks and strokes" and emphasized that Vioxx was "innovative, effective and safe."

76. In September 2001, the FDA sent a warning letter to Merck identifying Vioxx marketing materials and a press release that violated the Federal Food, Drug and Cosmetic Act because they minimized the cardiovascular findings observed in the VIGOR study, failed to present significant risks associated with Vioxx and made several unsubstantiated superiority claims with regard to other NSAIDs. The FDA specifically faulted Merck for downplaying the cardiovascular risks of Vioxx: "Your promotional campaign discounts the fact" that in the trial, "patients on Vioxx were observed to have a four to five-fold increase" in heart attacks compared with patients on naproxen. The FDA also warned Merck that its recent press releases "confirming the favorable cardiovascular safety profile of Vioxx" were "simply incomprehensible" given the rate of heart attacks and "serious cardiovascular events compared to naproxen."

77. Merck responded to this warning letter by pulling or revising the complained-of promotional materials, but persisted in refusing to include a cardiovascular warning in any of its direct-to-consumer advertisements. But Merck's misleading statements were already in the market and influencing the demand for its products. As Merck noted in its 2003 annual report, Vioxx is the best selling arthritis and pain medicine.

78. In April 2002, after fourteen months of negotiations with the FDA had resulted in the creation of a satisfactorily vague cardiovascular warning, Merck issued a press release that entirely minimized the importance of the risks it had been required to disclose: "The significance of the cardiovascular findings from [the VIGOR study] is unknown... Merck is confident in the efficacy and safety profile of Vioxx." Thus, while someone with enough medical knowledge to make sense of Merck's warning could have made sense of what Merck had known for years, it was still highly unlikely that the average consumer understood Vioxx to pose any serious cardiovascular risk.

E. Doubts Arise Over Merck Attacks

79. John Abramson, a family doctor and clinical instructor at Harvard Medical School, scrutinized detailed data on the Vigor trial provided by Merck to the FDA and posted on the FDA Web site. In a book published this summer, "Overdosed America: The Broken Promise of American Medicine," he concluded that even those without a history of heart trouble doubled their risk of developing a cardiovascular problem by taking Vioxx instead of naproxen.

80. Gregory Curfman, executive editor of the New England Journal, says the journal "didn't have all the details that the FDA had later on." Given the available data, he says editors "spent a great deal of time trying to make sure that these unexpected cardiovascular side effects were fairly and accurately represented" in the article.

81. By 2001, the Vigor data had clearly caused the debate to shift. The main question was no longer whether Vioxx lacked the benefits of older painkillers and if so whether that was significant. Now the issue was squarely Vioxx itself: Was the drug intrinsically risky?

82. In February 2001, the FDA presented its analysis of the Vigor data to an agency advisory committee. It showed that the number of people who had a digestive problem while taking naproxen was about double the figure for Vioxx takers -- but that

difference was almost exactly the same as the additional number of Vioxx users who suffered a cardiovascular problem such as a stroke.

83. FDA officials wanted to highlight the cardiovascular risk prominently on Vioxx's label. Merck resisted, complaining that the agency was putting more weight on the negative findings than on the positive gastrointestinal aspects. In the end, the two sides compromised. The new Vioxx label, which went into effect in April 2002, listed the good news about fewer upset stomachs first. Then it added two tables with the bad news about more heart attacks and strokes.

84. The agency, meanwhile, had become increasingly concerned about Merck's marketing of the drug to doctors. It complained in a September 17, 2001, warning letter about a Merck-sponsored presentation by a doctor in June 2000. The doctor had said the Vigor trial showed that naproxen was "a wonderful drug" for reducing the risk of heart problems – not that there was anything wrong with Vioxx. Such statements, the FDA said, "minimized the potentially serious cardiovascular findings" of Vigor.

85. A Merck internal marketing document reviewed by The Wall Street Journal, addressed to "all field personnel with responsibility for Vioxx," provided an "obstacle handling guide." If a doctor said he was worried that Vioxx might raise the risk of a heart attack, he was to be told that the drug "would not be expected to demonstrate reductions" in heart attacks or other cardiovascular problems and that it was "not a substitute for aspirin." This wasn't a direct answer.

86. One training document is titled "Dodge Ball Vioxx" and consists of 16 pages. Each of the first 12 pages lists one "obstacle," apparently representing statements that might be made by a doctor. Among them are, "I am concerned about the cardiovascular effects of Vioxx" and "The competition has been in my office telling me

that the incidence of heart attacks is greater with Vioxx than Celebrex." The final four pages each contain a single word in capital letters: "DODGE!"

87. Merck also went on the offensive against academic researchers who began to question Vioxx's safety. Gurkirpal Singh of Stanford University, a prominent Cox-2 expert who was giving lectures sponsored by Merck and other companies, says he pressed Merck repeatedly for more cardiovascular safety data. When Merck refused, Dr. Singh added a slide to his presentations that showed a man – representing the missing data -- hiding under a blanket. "This was the first time they didn't answer my questions," he says. "With Vigor, suddenly it was a clampdown."

88. Merck canceled several presentations by Dr. Singh that it had been scheduled to sponsor, and it didn't stop there. In October 2000, a Merck official, Louis Sherwood, called James Fries, a Stanford University Medical School professor, to complain that Dr. Singh's lectures were "irresponsibly anti-Merck and specifically anti-Vioxx," as Dr. Fries described the call in a January 2001 letter to Mr. Gilmartin, the Merck chief executive. The Merck official "suggested that if this continued, Dr. Singh would 'flame out' and there would be consequences for myself and for Stanford," Dr. Fries wrote.

89. Dr. Fries struck back. "There is a line that you can't go across. ... It had gone over that line," he says. He wrote to the Merck chief that researchers at several other top medical schools complained about "a consistent pattern of intimidation of investigators by Merck" on Vioxx.

90. Mr. Gilmartin responded that Merck had a "deep and abiding commitment to the highest ethical standards in all our dealings with physicians and other healthcare providers." Dr. Fries and other researchers mentioned in the letter say the company did try to repair relations subsequently. Dr. Singh, now an adjunct clinical professor at Stanford, says he stopped using the blanket slide after Merck gave him more data.

91. According to the WALL STREET JOURNAL,[4] Lee Simon, a rheumatologist at Beth Israel Deaconess Medical Center in Boston, says he publicly mentioned data showing Vioxx might be associated with a risk of high blood pressure and swelling. While Dr. Simon was closely involved with research on the rival Cox-2 drug Celebrex, he had worked with Merck in another area. Merck's Dr. Sherwood called Dr. Simon and one of his superiors at the hospital to complain that Dr. Simon's lectures were slanted against Vioxx.

92. "I was shocked that there was a phone call made like that," Dr. Simon says. "The company was attempting to suppress a discussion about this data."

93. In August 2001, researchers at the Cleveland Clinic published an analysis in the Journal of the American Medical Association that once again raised concerns about Vioxx's cardiovascular risks. Before it came out, Merck's Dr. Reicin and other officials met with the authors, arguing that "they didn't think there was a problem with the drug," says Steven Nissen, one of the Cleveland Clinic researchers. The company also asked the journal to run a Merck rebuttal but it refused, people with knowledge of the matter said at the time.

94. One of Merck's most aggressive moves came against Joan-Ramon Laporte of the Catalan Institute of Pharmacology in Barcelona, Spain. In the summer of 2002, a publication of the institute edited by Dr. Laporte repeated criticisms of Merck's handling of Vioxx that had been published in the British journal Lancet. Soon after, Dr. Laporte says, Merck officials sent him a "rectification" to publish, but he responded that there would be no correction. After Merck officials approached him twice more, the company filed suit in a Spanish court against Dr. Laporte and the institute, taking advantage of a Spanish law that allows plaintiffs to demand a public correction of inaccurate published information.

[4] 11/1/2004.

95. In January of this year, a judge ruled that Dr. Laporte's publication accurately reflected the medical debate about the cardiovascular safety of Vioxx, and ordered Merck to pay court costs.

96. This March, Dr. Laporte was a featured speaker at an annual update on the pharmaceutical world for about 1,000 Spanish family physicians. Merck had helped pay for the meeting for the previous eight years. It contacted the organizer, Ramon Morera i Castell, and told him that the company "preferred" if Dr. Laporte stayed off the program this year, says Dr. Morera. After Dr. Morera rejected the request, Merck withdrew its financing -- about $140,000. Though there wasn't any specific threat, "the message was clear," says Dr. Morera.

F. The Withdrawal of Vioxx

97. On September 30, 2004, the Center for Drug Evaluation and Research of the Food and Drug Administration issued a Memorandum concluding that Vioxx has adverse cardiovascular effects, which were evident as early as the 2000 VIGOR study: "***Rofecoxib increases the risk of serious coronary heart disease defined as acute myocardial infarction and sudden cardiac death***. . . . The observation of an increased risk was first noted with the VIGOR trial, where a 5-fold difference in risk was found between high-dose rofecoxib and naproxen. ***The manufacturer attributed this difference to a never before recognized protective effect of naproxen.*** To explain a 5-fold difference, naproxen would have had to be one of the most potent and effective cardio-protectants known. Three cohort studies and the present nested case-control study found no evidence of cardio-protection with naproxen. The three case-control studies that reported a protective effect were misleading. When analyzed in a manner comparable to the present study, ***no protective effect is shown***."[5]

[5] David J. Graham, MD, MPH, Associate Director for Science, Office of Drug Safety, Center for Drug Evaluation and Research, FDA, *Risk of Acute Myocardial Infarction and Sudden Cardiac Death in Patients Treated with COX-2 Selective and Non-selective NSAIDs* 13 (Sept. 30, 2004).

98. On that same day, September 30, 2004, Merck issued a press release announcing the withdrawal of Vioxx based on "new" data indicating an increased risk of cardiovascular events, such as heart attack and stroke for those taking the drug eighteen months or longer.[6] The decision came after the Data Safety Monitoring Board for an ongoing study of Vioxx (APPROVe) recommended that the study be stopped early for safety reasons based on the first three years of results.[7] APPROVe, or Adenomatous Polyp Prevention on Vioxx, was a trial of rofecoxib for the prevention of recurrence of colorectal polyps in patients with a history of colorectal adenomas. An article in The Lancet, a respected British medical journal, pointed out that the "voluntary withdrawal of rofecoxib by its manufacturer, Merck, on the basis of a fairly small trial that was designed for a different purpose raises several questions."[8] The critical question is when Merck knew that Vioxx was associated with an unacceptably high risk of adverse cardiovascular events, such as heart attack and stroke.

99. To establish whether robust evidence on the adverse effects of rofecoxib was available before the withdrawal of Vioxx from the market, meta-analysis of randomized controlled trials and observational studies was conducted and its results were recently published in The Lancet: "***Our cumulative meta-analysis of randomized controlled trials indicates that an increased risk of myocardial infarction was evident from 2000 onwards.*** At the end of 2000, the effect was both substantial and unlikely to be a chance finding. We found an increased risk of myocardial infarction in trials of both short and long duration, which is in contrast to the unpublished results from the APPROVe trial. . . . [T]he reassuring statement by Merck, that there is no excess risk in the first 18 months, is not supported by our data. . . . [D]ata from these studies indicate

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[6] Merck, *Merck Announces Voluntary Withdrawal of VIOXX*, available at http://www.vioxx.com/vioxx/documents/english/vioxx_press_release.pdf (accessed Nov. 5, 2004).

[7] FDA, *FDA Public Health Advisory: Safety of Vioxx*, available at http://www.fda.gov/cder/drug/infopage/vioxx/PHA_vioxx.htm (accessed Nov. 5, 2004).

[8] Peter Juni, et al., THE LANCET, *Risk of Cardiovascular Events and Rofecoxib: Cumulative Meta-Analysis* 4 (Nov. 5, 2004).

that if a protective effect of naproxen exists, it is . . . not large enough to explain the findings of VIGOR. By contrast to our findings, two earlier meta-analyses from Merck Research Laboratories showed no evidence of a rise in cardiovascular risk or an increase in risk that was restricted to trials comparing rofecoxib with naproxen. . . . ***To clarify the reasons behind the misleading results of Merck's meta-analysis of cardiovascular events in clinical trials of rofecoxib will be important.*** . . . If Merck's statement in their recent press release that 'given the availability of alternate therapies, and the questions raised by the data, we concluded that a voluntary withdrawal is the responsible course to take' was appropriate in September, 2004, then ***the same statement could and should have been made several years earlier, when the data summarised here first became available. Instead, Merck continued to market the safety of rofecoxib.***"[9]

100. Merck has agreed to reimburse patients for Vioxx purchased but not used as of September 30, 2004. But this does nothing for the millions of patients in Arizona who have already purchased and consumed Vioxx and who paid more than they would have or should have because it was advertised as a premium drug with reduced side effects and/or who would not have purchased Vioxx at all had they know about its adverse cardiovascular effects.

V. CLASS ALLEGATIONS

101. Plaintiff Feinberg brings this action on behalf of himself and a class defined as follows: All persons or entities in Massachusetts who purchased Vioxx in the four (4) years preceding the filing of this Complaint up to and including the present.

102. The Class consists of millions of individuals and entities throughout Arizona, making individual joinder impractical. The disposition of the claims of the Class members in a single class action will provide substantial benefits to all parties and to the Court.

[9] Peter Juni, et al., THE LANCET, *Risk of Cardiovascular Events and Rofecoxib: Cumulative Meta-Analysis* 5-7 (Nov. 5, 2004).

103. The claims of the representative Plaintiff are typical of the claims of the Class because he, like all Class members, has purchased Vioxx and has been harmed by Defendant's misconduct because he would not have purchased Vioxx had he known the truth.

104. The factual and legal bases of Defendant's misconduct are common to all Class members and represent a common thread of deception and other misconduct resulting in injury to the representative Plaintiff and all members of the Class.

105. There are many questions of law and fact common to the representative Plaintiff and the Class, and those questions substantially predominate over any questions that may affect individual Class members. Common questions include, but are not limited to, the following:

(a) Whether Defendant's active concealment of and/or failure to disclose the true nature of Vioxx had the capacity to mislead or deceive within the common law of Massachusetts;

(b) Whether Defendant's active concealment of and/or failure to disclose the true nature of Vioxx is unlawful within the common law of Massachusetts;

(c) Whether Defendant's knowingly and with intent to sell represented that Vioxx has characteristics, uses, benefits, or qualities that it does not have and advertised it with intent not to sell it as advertised;

(d) Whether Defendant should be declared financially responsible for notifying all Class members of the true nature of Vioxx; and

(e) Whether Defendant should be ordered to disgorge, for the benefit of the Class, all or part of its ill-gotten profits received

from the sale of Vioxx, and/or to make restitution and pay damages to Plaintiff and the members of the Class.

106. Plaintiff will fairly and adequately represent and protect the interests of the Class. Plaintiff has retained counsel with substantial experience in prosecuting consumer class actions, including actions involving pharmaceutical sales. Plaintiff and his counsel are committed to vigorously prosecuting this action on behalf of the Class, and have the financial resources to do so. Neither Plaintiff nor his counsel has any interests adverse to those of the Class.

107. Plaintiff and the members of the Class suffered, and will continue to suffer, harm as a result of Defendant's unlawful and wrongful conduct. A class action is superior to other available methods for the fair and efficient adjudication of the controversy. Absent a class action, most members of the Class likely would find the cost of litigating their claims to be prohibitive, and will have no effective remedy at law. Because of the relatively small size of each individual Class member's claims, few Class members likely could afford to seek legal redress for Defendant's misconduct. Absent a class action, Class members will continue to suffer harm and Defendant's misconduct will proceed without remedy. The class treatment of common questions of law and fact is also superior to multiple individual actions or piecemeal litigation in that it conserves the resources of the courts and the litigants, and promotes consistency and efficiency of adjudication. Additionally, Defendants have acted and failed to act on grounds generally applicable to the representative Plaintiff and the Class and require Court imposition of relief as to the Class as a whole.

FIRST CAUSE OF ACTION

COMMON LAW FRAUD AND NEGLIGENT MISREPRESENTATION

108. The preceding paragraphs of this Complaint are realleged and incorporated by reference as if fully set forth herein. Plaintiff asserts this claim on behalf of himself and the members of the Class.

109. Defendant's actions, as complained of herein, constitute unfair, and deceptive unlawful practices committed in violation of the common law of fraud and negligent misrepresentation.

110. For example, Defendants violated the law by engaging in the following conduct:

(a) Defendant's promotions of Vioxx as a safe drug for the treatment of pain and as having fewer side effects than comparable drugs on the market were deceptive, unfair, and unlawful in that Vioxx actually had an unacceptably high risk of adverse cardiovascular events and was promoted solely for financial reasons and not due to any material increase in medical safety;

(b) Defendant's conduct was unfair, unlawful and deceptive in that Defendant knew Vioxx was unsafe and increased the risk of adverse cardiovascular events, such as heart attack and stroke, to unacceptable levels, but omitted to disclose these facts to doctors and patients until September 2004;

(c) Defendants omitted material information known to them in order to induce doctors to prescribe Vioxx and consumers to purchase Vioxx at a price that exceeded its actual worth; and

(d) Defendants committed unlawful acts by promoting and advertising Vioxx in a manner that violated the Federal Food, Drug and Cosmetic Act. *See* 21 U.S.C. §§ 331(a) and (b), 352(a), (f) and (n) and 355(a).

111. All of the conduct alleged herein occurred in the course of Defendant's business. Defendant's wrongful conduct was part of a pattern or generalized course of conduct repeated on thousands of occasions daily.

112. Plaintiff and the Class have all been directly and proximately injured as the result of Defendant's wrongful conduct.

113. Plaintiff requests that this Court enter such orders or judgments as may be necessary to restore to any person in interest, any money which may have been acquired by means of such unfair practices.

SECOND CAUSE OF ACTION

RESTITUTION/UNJUST ENRICHMENT

114. The preceding paragraphs of this complaint are realleged and incorporated by reference and asserted by Plaintiff on behalf of himself and members of the Class.

115. To the detriment of Plaintiff and members of the Class, Defendant has been, and continues to be, unjustly enriched as a result of the unlawful and/or wrongful collection of, *inter alia*, payments for Vioxx.

116. Defendant has unjustly benefited through the unlawful and/or wrongful collection of, *inter alia*, payments for Vioxx and continues to so benefit to the detriment and at the expense of Plaintiff and members of the Class.

117. Accordingly, Plaintiff and members of the Class seek full restitution of the Defendant's enrichment, benefits and ill-gotten gains acquired as a result of the unlawful and/or wrongful conduct alleged herein.

VI. PRAYER FOR RELIEF

WHEREFORE, Plaintiff and members of the Class request that the Court enter an order or judgment against Defendant as follows:

A. Certification of the Class and appointment of Plaintiff as Class Representative and his counsel of record as Class Counsel;

B. Award Plaintiff and each Class Member appropriate damages, including the restitution and/or disgorgement of all unlawful or illegal profits received by Defendant as a result of the unfair, unlawful and/or deceptive conduct alleged in this Complaint;

C. Prejudgment and post-judgment interest from the date of the harm at the highest rate allowed by law;

D. Appropriate injunctive relief;

E. An order awarding Plaintiff the costs of bringing this suit, including attorneys' fees; and

F. All other relief to which Plaintiff and members of the Class may be entitled at law or in equity.

DATED: February 17, 2005.

HAGENS BERMAN SOBOL SHAPIRO LLP

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Attorneys for Plaintiffs

United States District Court
District of Massachusetts

04 12166 RCL

FRANK R. SAIA, individually and on behalf of all others similarly situated,

Plaintiff,

v.

MERCK & CO., INC.,

Defendant.

Civil Action No.

MAGISTRATE JUDGE Bowler

PLAINTIFF DEMANDS A TRIAL BY JURY

RECEIPT # 54312
AMOUNT $150
SUMMONS ISSUED YES
LOCAL RULE 4.1
WAIVER FORM
MCF ISSUED
BY DPTY. CLK Fyml
DATE 5/5/05

CLASS ACTION COMPLAINT

This is an action brought by Plaintiff on behalf of himself and all others similarly situated, who have ingested the non-steroidal, anti-inflammatory pain medication called Vioxx (chemical name "rofecoxib"). This action seeks damages and the establishment of a medical monitoring program on behalf of the Plaintiff and the Class to ensure prompt diagnosis and treatment for Vioxx-related adverse health effects for all class members who acquired and used Vioxx.

I. INTRODUCTION

1. Plaintiff Frank R. Saia brings this Civil Action for damages and medical monitoring as a result of economic harm suffered from the purchase and use of Vioxx and the increased risk of health problems causally connected to the consumption of Vioxx.

2. Plaintiff purchased Vioxx and ingested the drug on a regular basis, as prescribed by his physician.

3. Ingestion of Vioxx has been linked to an increased risk of adverse health effects

for users, including the increased risk of cardiovascular events such as heart attack and stroke.

4. The Food and Drug Administration ("FDA") approved Vioxx in 1999 for the reduction of pain and inflammation caused by osteoarthritis, as well as for acute pain in adults and for the treatment of menstrual pain. The FDA accelerated the approval process of Vioxx because of a perceived benefit to consumers over the available alternatives at the time, including ibuprofen and naproxen. Subsequently, the FDA approved Vioxx to treat the signs and symptoms of rheumatoid arthritis in adults and children.

5. In June 2000, Merck submitted to the FDA a safety study called VIGOR (Vioxx Gastrointestinal Outcomes Research) that found an increased risk of serious cardiovascular events including heart attacks and strokes, in patients taking Vioxx compared to patients taking naproxen. Defendant attributed these results to a purported "cardio-protective effect" of naproxen.

6. Despite reports over the next few years to the contrary, Defendant continued to maintain that Vioxx did not increase a user's risk of cardiovascular events such as heart attack and stroke.

7. On September 30, 2004, Defendant revealed that Vioxx doubled the risk of heart attack and stroke to consumers who took the drug for longer than 18 months, as compared to subjects taking a placebo. As a result of this revelation, Vioxx was withdrawn from the market worldwide.

8. However, the withdrawal from the market came after Plaintiff Frank R. Saia and other similarly situated class members ingested the drug without notice of the inherent risks to their health. As such, Plaintiff and the Class suffered harm in that their consumer choice was distorted by misleading representations by Defendant, and now Plaintiff and the Class are at an

increased risk of cardiovascular events such as heart attack and stroke and thus require medical monitoring.

II. PARTIES

9. Plaintiff Frank R. Saia is a resident of the Commonwealth of Massachusetts and acquired and ingested Vioxx.

10. Defendant Merck & Co., Inc. ("Merck" or "Defendant") describes itself as a global research-driven pharmaceutical company which discovers, develops, manufactures and markets a broad range of products to improve human and animal health, directly and through joint ventures. Merck is incorporated under the laws of the State of New Jersey with its principal place of business at One Merck Drive, Whitehouse Station, New Jersey. Defendant was in the business of profiting from the design, manufacture, marketing, distribution and/or sales of the brand-name prescription drug Vioxx.

III. JURISDICTION AND VENUE

11. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between Plaintiff and Defendant and because the amount in controversy exceeds $75,000, exclusive of interest and costs.

12. Venue is properly laid in this district pursuant to 28 U.S.C. § 1391(a) because Defendant was engaged in the business of marketing and distributing Vioxx in the Commonwealth of Massachusetts. In addition, a substantial part of the events giving rise to the claims occurred in this district.

IV. FACTUAL BACKGROUND

13. At all times relevant, Defendant Merck, itself or by use of others, did research, develop, manufacture, create, design, test, label, sterilize, package, distribute,

supply, market, sell, promote, advertise, and otherwise distribute in interstate commerce, the pharmaceutical product Vioxx.

14. Vioxx belongs to a class of drugs called "non-steroidal anti-inflammatory drugs," or "NSAIDs." NSAIDs reduce pain by blocking the body's production of enzymes called cyclooxygenase, or "COX," of which there are two forms: COX-1 and COX-2. Most traditional NSAIDs (such as ibuprofen and naproxen) work by blocking the COX-1 enzyme, which reduces pain but may lead to gastroinstestinal perforations and bleeds.

15. Vioxx, it is believed, blocks the COX-2 enzyme that triggers pain and inflammation while sparing the COX-1 enzyme that helps maintain normal stomach lining. It is indicated for treating the signs and symptoms of osteoarthirtis and rheumatoid arthritis, management of acute pain in adults, and treatment of primary dysmenorrhea.

16. Vioxx did not promise to be any more effective than traditional NSAIDs, like ibuprofen and naproxen, at treating inflammation and pain. The sole advantage of Vioxx over other NSAIDs was its purported improved safety profile.

17. Vioxx is a brand name used by Merck to market and distribute rofecoxib. Vioxx was approved for marketing based on information in the New Drug Application submitted by Merck to the FDA. The FDA put Vioxx on a fast-track approval process that lasted approximately 6 months. Defendant obtained FDA approval on Vioxx in or around May of 1999 and began its distribution and sale throughout the United States, including Massachusetts, in May of 1999.

18. Defendant concealed the serious cardiovascular risks associated with Vioxx because a successful launch of Vioxx was viewed as critical for Merck and safety concerns over hypertension, edema and/or cardiovascular events would have drastically impacted

Merck's positioning in the market as compared to the competing drug, Celebrex (clecoxib), which was placed into the market by Merck competitors Pharmacia and Pfizer some three months prior to the launch of Vioxx.

19. Merck knowingly chose to place these adverse health risks on its consumers despite its knowledge at product launch and in post-marketing data thereafter that use of Vioxx carried significant risk factors. These adverse effects were realized in adverse event reports, in clinical trials adjudicated by primary investigators with Merck's assistance, and in one or more studies shortly after market launch, which showed statistically significant increases in adverse cardiovascular events among Vioxx users.

20. On or about December 16, 1999, the FDA called Defendant to task for its materially false and misleading marketing and promotional materials. The FDA sent Defendant an official letter (the "First FDA Warning Letter") admonishing it that the "promotion pieces...that promoted VIOXX (rofecoxib) ... are false and misleading because they contain misrepresentations of VIOXX's safety profile, unsubstantiated comparative claims, and are lacking in fair balance."

21. In March 2000, Defendant released the results of a Merck-sponsored VIGOR Study, which had begun in or around January of 1999. The VIGOR Study revealed, among other things, "significantly fewer heart attacks were observed in patients taking Naproxen (0.1 percent) compared to the group taking VIOXX 50 mg (0.5 percent) in this study. There was no difference in cardiovascular mortality between the group treated with VIOXX or Naproxen."

22. Defendant attributed the difference in rates of cardiovascular events to the fact that naproxen has "cardio-protective effects," and not to an increased risk of cardiovascular events attributable to Vioxx.

23. In designing the VIGOR Study, Merck took the exceptional step of including an "external Vascular Event Committee (VEC), containing three separate subspecialty committees (cardiac, cerebrovascular, and peripheral), [] for surveillance, monitoring, and adjudication of vascular events occurring in COX-2 inhibitor trials." According to a July 13, 2002 article that appeared in the British medical journal, *The Lancet*, Merck "apparently was aware of possible myocardial toxicity before the [VIGOR] trial, because it set in place a separate adjudication procedure to study the event."

24. While VIGOR did demonstrate that Vioxx reduced the incidence of serious gastrointestinal side effects as compared to naproxen, it did not demonstrate an improved safety profile for Vioxx. The VIGOR data revealed that:

a. Patients on Vioxx were five times more likely to suffer a heart attack as compared to patients on naproxen;

b. Patients on Vioxx were 2.3 times more likely to suffer serious cardiovascular disease (including heart attacks, ischemic stroke, unstable angina, and sudden unexplained death) as compared to patients on naproxen;

c. According to the FDA, "[e]valuation of safety by routine parameters showed no advantege of [Vioxx] rofecoxib over Naproxen; and

d. Patients on Vioxx actually suffered *more* cases of serious disease (either gastrointestinal or cardiovascular) than did naproxen users (61 and 57 cases respectively).

25. In industry sponsored studies presented at the European United League Against Rheumatism (EULAR), an organization in which Merck is a member and corporate sponsor, in June of 2000, it was shown that Vioxx use resulted in a statistically significant increase in hypertension and myocardial infarction. Merck denied these studies as to the hypertension

problems in the official publication of the American Pharmaceutical Association, Pharmacy Today. (*Spin War Aside. Lessons Emerge From Cox-2 Trials*, August 2000, page 3).

26. Merck continued to deny the ill health effects associated with Vioxx while at the same time reaping the profits obtained through the non-disclosure. Merck engaged in a massive advertising and sampling program and gained continued increases in market share, which enhanced Merck's financial bottom line. The effect was a more than $2 billion profit for Merck in 2000 and a 23 percent market share.

27. Merck continued to withhold relevant data from the public throughout the Class Period. For example, in November of 2000, Merck caused the publication of a study in the New England Journal of Medicine and knowingly downplayed and/or withheld from this publication the severity of cardiovascular risks associated with Vioxx consumption over Naproxen consumption.

28. On February 8, 2001, Merck submitted the results of the VIGOR Study to the FDA Arthritis Advisory Committee as part of Merck's application to modify the prescribing information for Vioxx to reflect the Drug's purported gastrointestinal ("GI") benefits.

29. In considering the VIGOR Study results, however, the FDA Advisory Committee concluded (in February 2001) Vioxx has no safety advantage over the generic drug naproxen, a drug that sells for a fraction of the cost of Vioxx. According to the *FDA Advisory Committee Briefing Document, VIOXX Gastrointestinal Safety*, dated February 8, 2001: "[I]n the VIGOR Study the potential advantage of decreasing the risk of complicated [GI side effects] was paralleled by the increased risk of developing cardiovascular thrombotic events."

30. According to a memo prepared by an Advisory Committee member, Lourdes Villalba, M.D., dated February 8, 2001, which discusses the "Overall Safety" of Vioxx, "the

VIGOR Study found there were more overall deaths among Study participants taking Vioxx than those taking naproxen (22 and 15, respectively).

31. The VIGOR results showed that 50mg doses of Vioxx increased the risk of heart attacks and cardiovascular disease. Faced with this threat to the success of its new blockbuster drug, Defendant offered an unfounded explanation for the negative cardiovascular findings of the VIGOR Study. Defendant asserted that the dramatically increased risk of heart attacks in persons taking Vioxx 50mg was not due to Vioxx; rather, Defendant claimed naproxen was cardio-protective and thus dramatically reduced the risk of heart attacks. Tellingly, the marketers of naproxen have never promoted their drug as being cardio-protective.

32. On August 22, 2001, the *Journal of the American Medical Association* ("JAMA") published an article authored by cardiologists Eric J. Topol and Steven E. Nessen of the Cleveland Clinic Foundation entitled "*Risk of Cardiovascular Events Associated With Selective Cox-2 Inhibitors*," which reported the results of a study of Vioxx and Celebrex. The JAMA article reported the findings of the Cleveland Clinic's study that "[c]urrent data would suggest that use of these so-called 'COX-2 inhibitors' might lead to increased cardiovascular events."

33. The day before the JAMA article was published, *Bloomberg News* reported that Merck commented, with regard to the article, "We have additional data beyond what they cite, and the findings are very, very reassuring. Vioxx does not result in any increase in cardiovascular events compared to placebo." Further, on August 23, 2001, the day after the article was published, Merck stated in a press release, "the Company stands behind the overall and cardiovascular safety profile...of Vioxx."

34. In a follow-up study reported in the Journal of the American College of

Cardiology on or about February 6, 2002, Dr. Richard J. Bing conducted scientific testing and confirmed that the Cox-2 inhibitor tips the balance of prostacyclin/thromboxane in favor of thromboxane, leading to increased vascular and thrombotic events.

35. In September 2001, the FDA sent Defendant another warning letter (the "Second FDA Warning Letter") which again warned Defendant that Merck's marketing of VIOXX was "false, lacking in fair balance, or otherwise misleading..." The Second Warning Letter went on to advise Defendant that Merck's marketing "minimize[s] the potential serious cardiovascular findings that were observed in the VIGOR Study, minimize[s] the VIOXX/Coumadin drug interaction, omit[s] crucial risk information associated with VIOXX therapy, contain[s] unsubstantiated comparative claims, and promote[s] unapproved uses."

36. The Second Warning Letter also reprimanded Merck for:

> "assert[ing] that Vioxx does not increase the risk of [heart attacks] and that the VIGOR finding is consistent with naproxen's ability to block platelet aggregation like aspirin. That is a possible explanation, but you fail to disclose that your explanation is hypothetical, has not been demonstrated by substantial evidence, and that there is another reasonable explanation, that Vioxx may have pro-thrombotic properties."

37. Defendant denied reports concerning the increased risk of cardiovascular problems as inaccurate and inconclusive. For example, on May 22, 2001, Merck issued a press release through the *PR Newswire* that stated, among other things: "In response to news and analyst reports of data the Company first released a year ago, Merck & Co., Inc. today reconfirmed the favorable cardiovascular safety profile of Vioxx."

38. The theory that naproxen had a cardioprotective effect and therefore accounted for the higher cardiovascular risks among Vioxx users was debunked in approximately January of 2002 by a Vanderbilt University School of Medicine human epidemiologic peer-reviewed

study. The study was published in *The Lancet*, and concluded that there is an absence of a protective effect of naproxen or other non-aspirin non-steroidal anti-inflammatory drugs on risk of coronary heart disease. Ray, W., et. al., *Non-Steroidal Anti-Inflammatory Drugs and Risk of Serious Coronary Heart Disease: An Observational Cohort Study*, *The Lancet*, 359: 118-123, Jan. 12, 2002.

39. The FDA's Adverse Reporting System ("AERS") database is a computerized system for collecting and maintaining information about adverse events reported by drug manufacturers, health professional, and others. The system contains adverse events detected and reported after marketing of the drug.

40. According to AERS, through October of 2003, almost 2,000 adverse cardiovascular events were experienced by persons taking Vioxx, including myocardial infarctions, cardiac arrests, and cardiac failures. These cardiac events reported to the FDA, which, according to some measures, represent underreporting of as much as 99%, resulted in such outcomes as hospitalization, life threatening conditions, and even death.

41. On October 22, 2003, *Reuters* published an article that stated "arthritis drug is suffering from clinical trial data suggesting it might slightly raise the risk of heart attacks, and the growing perception that its pain-fighting capabilities are no better than traditional painkillers."

42. On October 30, 2003, in an article entitled "Vioxx Study Sees Heart-Attack Risk," *The Wall Street Journal* reported that another study, sponsored by Merck, presented at the annual meeting of the American College of Rheumatology, confirmed an increased "risk of heart attacks in patients taking the pill [Vioxx]." According to *The Wall Street Journal* article, within the first 30 days of taking Vioxx, the risk of a heart attack was increased 39% as

compared to Vioxx's competitor, Celebrex.

43. At all times relevant to this litigation, Defendant Merck had a significant market share based upon claims of Vioxx's efficacy, a very aggressive marketing program which involved financial incentives to sales teams, infusion of some 700 new sales representatives, and a massive advertising and sampling program.

44. If Defendant had not engaged in this conduct, consumers, including Plaintiff, would have known the true risks of ingesting Vioxx and would have switched from Vioxx to safer products or refrained wholly from its use.

45. The marketing strategies of the Defendant targeted Plaintiff and the other Class members to induce them to purchase Vioxx. At the time the Defendant distributed, manufactured and marketed Vioxx, Defendant intended that Plaintiff would rely on the marketing, advertisements and product information propounded by Defendant, as well as Defendant's omission of relevant negative information from such materials.

46. From the initial marketing of Vioxx until April 2002, the safety label for Vioxx set forth an explicit warning concerning "Gastrointestinal (GI) Effects." Specifically, the safety label warned of the "Risk of GI Ulceration, Bleeding, and Perforation." Nowhere within the safety label did Defendant make full or adequate disclosure of the cardiovascular safety issues related to Vioxx.

47. After reviewing the results of the VIGOR study and other available data from controlled clinical trials, the FDA consulted with its Arthritis Advisory Committee. In April 2002, pursuant to the review by the FDA and resultant instructions, Merck implemented labeling changes for Vioxx to reflect the findings from the VIGOR study. The labeling changes included information about the occurrence of cardiovascular events, including heart

attack and stroke, in some patients. At no time did the safety label disclose the level of risk that consumers were subjected to as a result of their ingestion of Vioxx. In fact, Merck continued to stand by the "safety profile" of Vioxx.

48. The April 2002 labeling changes were insufficient to put the consuming public on notice of the extent of the risk of adverse health effects that use of Vioxx presented.

49. Thus, despite knowledge in its clinical trials and post-marketing reports, studies and information relating to cardiovascular-related adverse health effects, Defendant promoted and market Vioxx as safe and effective for persons such as Plaintiff and members of the Class.

50. Merck failed to reveal the true connection between use of Vioxx and cardiovascular events until September 30, 2004.

CLASS ACTION ALLEGATIONS

51. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(2) and/or (b)(3), on behalf of a Class consisting of all persons who acquired and ingested Vioxx from May 21, 1999 to September 30, 2004, inclusive. Excluded from the Class are the affiliates and subsidiaries of the Defendant, the officers and directors of the Defendant; members of the immediate family of any excluded person, the legal representatives, heirs, successors and assigns of any excluded person, and any entity in which any excluded person has or had a controlling interest.

52. The members of the proposed Class are geographically disbursed throughout the United States and Massachusetts, and are so numerous that joinder of all of them is impracticable.

53. Plaintiff's class claims are typical of Class members' claims because each Class member was subject to a common course of conduct and pattern of practice perpetrated by

Defendant.

54. No conflict exists between Plaintiff and Class members because: (a) the claims of the named plaintiff are typical of the absent Class members' claims, (b) virtually all of the questions of law or fact at the liability stage are common to the class and predominate over any individual issues, such that by prevailing on her own claims, Plaintiff necessarily will establish Defendant's liability as to all class members, and (c) without the representation provided by Plaintiff herein, few class members will receive legal representation or redress for their injuries.

55. Plaintiff can and will fairly and adequately represent and protect the interests of the class and has no interests that conflict with or are antagonistic to the interests of the Class. Plaintiff has retained attorneys competent and experienced in class action litigation, consumer law and product liability.

56. There are issues of law common to the Class which predominate over any individual issues in the claims, including, but not limited to:

a. Whether Defendant designed, manufactured and/or marketed Vioxx with knowledge that it was a dangerously defective product;

b. Whether Defendant acted negligently in marketing and selling Vioxx;

c. Whether Defendant conducted, either directly or indirectly, adequate testing of Vioxx;

d. Whether Defendant failed to adequately warn consumers of the adverse health hazards caused by using Vioxx;

e. Whether Defendant falsely and fraudulently misrepresented in their advertising, promotional materials and other materials, among other things, the safety of using Vioxx;

f. Whether Defendant knowingly omitted, suppressed or concealed material facts about the unsafe and defective nature of Vioxx from

governmental regulators, the medical community and/or the consuming public;

g. Whether Defendant's conduct constituted an unfair, deceptive and/or unconscionable trade practice;

h. Whether Defendant's conduct constituted the knowing or intentional concealment, suppression or omission of material information intended to be relied upon by others in connection with the sale of Vioxx;

i. Whether Defendant's actions support a cause of action for medical monitoring;

j. Whether medical monitoring of Plaintiff and the Class who used Vioxx is reasonable necessary;

k. Whether the class is entitled to a return of the purchase price of Vioxx or other such relief.

57. Virtually all of the issues of fact in the class claims are common to the Class and predominate over any individual issues in the class claims.

58. A class action is superior to any other available method for the fair and efficient adjudication of this count, given that:

a. common questions of law and fact overwhelmingly predominate over any individual questions that may arise, such that there would be enormous economies to the courts and to the parties in litigating the common issues on a class-wide basis as opposed to a repetitive, individual basis, which could result in conflicting judgments and obligations for the parties;

b. the size of each Class member's individual damage claim typically is too small to make individual litigation against Defendant an economically viable alternative;

c. despite the relatively small size of individual Class members' claims, their aggregate volume, coupled with the economies of scale inherent in litigating similar claims on a common basis, will enable this case to be litigated as a class action on a cost-effective basis, especially when compared with the burden on the courts and the parties of conducting myriad individual litigations; and

d. no unusual difficulties are likely to be encountered in the management of this action as a class action.

Class certification is also appropriate pursuant to Federal Rule of Civil Procedure 23(b)(2) because Defendant has acted on grounds generally applicable to the Class, making appropriate equitable injunctive relief with respect to Plaintiff and the Class members. Specifically, Plaintiff seeks injunctive relief in the form of court-ordered medical monitoring and treatment of medical conditions which may befall those who used Vioxx.

COUNT I
(Fraud)

59. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein.

60. Defendant intentionally employed deceptive representations as to the risks and side effects of Vioxx in the marketing, promotion and sale of the drug to consumers, as set forth above.

61. Defendant's conduct included the issuance of the false and misleading representations and omissions of material facts regarding Vioxx's capabilities and the side effects of Vioxx upon which Plaintiff and the other members of the class relied.

62. Defendant failed to sell Vioxx in the manner and of the nature advertised or offered, and was unable to provide Vioxx in accordance with other terms or conditions.

63. The fraudulent practices of Defendant have directly, foreseeably, and proximately caused damages and injury to Plaintiff and the Class.

64. Defendant's conduct caused Class members to acquire and ingest Vioxx.

65. By reason of Defendant's unlawful conduct Plaintiff and the Class have suffered losses and are entitled to damages as defined in the statute, including exemplary damages, the

return of consideration paid and attorneys' fees, as specified therein.

COUNT II
(Medical Monitoring)

66. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein.

67. As a direct and proximate result of Defendant's acts and omissions as set forth herein, Plaintiff and the members of the Class were exposed to a hazardous substance and, as a result, suffer a significantly increased risk of contracting further serious injury or latent disease, including heart attack and stroke. This increased risk makes periodic diagnostic and medical examination reasonable and necessary. Easily administered, cost-effective monitoring and testing procedures exist which make the early detection and treatment of such injuries or disease possible and beneficial.

68. The recommended testing and monitoring procedures will be subject to expert testimony at the time of trial.

69. The increased susceptibility to injuries and irreparable threat to the health of Plaintiff and the Class resulting from their exposure to Vioxx can only be mitigated or addressed by the creation of a comprehensive medical monitoring program.

70. Plaintiff and the Class have no adequate remedy at law in that monetary damages alone cannot compensate for the continuing nature of the harm to them, and a monitoring program which notifies them of possible injury and aids in their diagnosis and treatment can prevent the greater harms which may not occur immediately and which may be preventable if proper research is conducted and the health risks are diagnosed and treated before they occur or worsen.

71. The susceptibility of Plaintiff and other Class members to heart attacks, strokes and other disorders is a result of their use of Vioxx. Early detection and diagnosis of these conditions is clinically invaluable because it can prevent and/or significantly delay resulting pain, suffering and/or death.

72. Without a court-approved and supervised medical monitoring program, Plaintiff and the Class will not receive prompt medical care which could detect injury and disease and prolong their productive life, increase prospects for improvement and minimize disability.

COUNT III
(Unjust Enrichment)

73. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein.

74. As a direct, proximate, and foreseeable result of Defendant's acts and otherwise wrongful conduct, Plaintiff and the Class were economically harmed. Defendant profited and benefitted from the sale of Vioxx, even as Plaintiff and the Class suffered this harm.

75. Defendant has voluntarily accepted and retained these profits and benefits, derived from consumers with full knowledge and awareness that, as a result of Defendant's unconscionable and intentional wrongdoing, consumers, including Plaintiff, were not receiving products of the quality, nature, fitness, or value that had been represented by Defendant or that reasonable consumers, expected. Plaintiff and the Class purchased medicine that they expected would improve their health, and instead found their health negatively affected.

76. By virtue of the conscious wrongdoing alleged in this Complaint, Defendant has been unjustly enriched at the expense of Plaintiff and the Class, who are entitled to in equity, and hereby seek, the disgorgement and restitution of Defendant's wrongful profits, revenue,

and benefits, to the extent, and in the amount, deemed appropriate by the Court; and such other relief as the Court deems just and proper to remedy Defendant's unjust enrichment.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief as follows:

1. For general damages in a sum in excess of the jurisdictional minimum of this Court;
2. Pre-judgment and post-judgment interest as provided by law;
3. Full refund of all purchase costs Plaintiff and the Class paid for Vioxx;
4. Compensatory damages in excess of the jurisdictional minimum of the Court, according to proof;
5. Consequential damages in excess of the jurisdictional minimum of the Court, according to proof;
6. Punitive and exemplary damages. In support of said damages, Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows:
   (a) Plaintiff is entitled to punitive damages because Defendant acted with malice and/or intentional and reckless indifference to Plaintiff's safety and well being. Defendant misled both the medical community and the public at large, including Plaintiff and the Class, by making false and misleading representations about the safety of Vioxx and failing to reveal relevant, negative information. Defendant understated and/or disregarded their knowledge of the serious and permanent adverse effects associated with the use of Vioxx despite available information demonstrating that their product was likely to cause serious, and sometimes, fatal side effects to users, like Plaintiff and other members of the Class.

   (b) Defendant was or should have been in the possession of evidence demonstrating that Vioxx caused serious adverse reactions. Nevertheless, Defendant continued to market Vioxx by providing false and misleading information as to the safety of the product to government officials, the medical community and the public.

   (c) Accordingly, punitive damages are warranted, and should be awarded to Plaintiff as determined at trial.
7. Attorneys' fees, expenses, and costs of this action;
8. Disgorgement of all profits associated with Vioxx;

9. Injunction requiring Defendant to fund a medical monitoring program to address the needs of the Class associated with the use of Vioxx; and

10. Such further relief as this Court deems necessary, just and proper.

PLAINTIFF DEMANDS A TRIAL BY JURY.

Dated: October 13, 2004

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DECLARATION OF MERLIN R. WILSON, M.D., F.A.C.P., F.A.C.R.

I, Merlin R. Wilson, M.D., F.A.C.P., F.A.C.R., under penalty of perjury, declare:

1. I am more than twenty-one years of age and competent to make this affidavit, which is based on my personal knowledge. The facts set forth herein are true and correct.

2. My academic credentials and professional experiences are broad and multidisciplinary. My undergraduate degree was in Biology. In 1968 I received an M.D. from Louisiana State University School of Medicine, New Orleans. In 1972 I completed a residency program in Internal Medicine at Charity Hospital New Orleans, LSU division, serving as Chief Medical Resident of the program from 1971 to 1972. In 1976 I completed a National Institutes of Health fellowship training in the Allergy-Immunology-Rheumatology Division of Scripps Clinic & Research Foundation in La Jolla, California. I am board-certified in Internal Medicine, and am a diplomat of the American Board of Internal Medicine with a subspecialty in Rheumatology. I am also board-certified by the American Board of Allergy & Immunology. I am a fellow of the American College of Physicians and the American College of Rheumatology. I am a Clinical Professor of Medicine at LSU Health Sciences Center and Tulane Medical School.

3. In addition to my formal education, I have evaluated and treated patients as both a practicing and teaching rheumatologist for over twenty-five years. Each year, I treat thousands of patients with pain primarily associated with the many different forms of arthritis, and I have also been responsible for managing high-risk patients afflicted with numerous other acute and chronic pain syndromes, as well as high-risk patients who have been diagnosed with cardiovascular disease. My medical practice sees hundreds of patients per month on a routine basis. I, along with my partner, set up this practice. I am completely familiar with the costs associated with the start-up of my practice.

4. I understand that this litigation involves the prescription medication VIOXX®. I had routinely prescribed VIOXX® for many years.

5. I am informed by attorneys for Merck that various putative class actions have been filed that seek medical monitoring for VIOXX® users in various states.

6. I am familiar with the basic tests and procedures necessary for monitoring patients for cardiovascular events, and the costs of those tests and procedures.

7. I do not believe any such medical monitoring over and above what is standard care for all patients is required by the ingestion of VIOXX®. Nor do I believe that any single appropriate monitoring regime could be implemented for all users of VIOXX®. However, notwithstanding these reservations, I have been asked to assess, based on my experience as a treating physician who has established his own practice, whether the start-up administrative costs for any medical monitoring regime for such a large group of individuals would exceed $75,000. My opinion is that it would.

8. Any type of medical monitoring fund that would fit the description of what Plaintiff alleges he will require has certain basic requirements for start-up before even a single patient can benefit from the fund. The medical monitoring scheme will require clerical staffing and computer systems to track patients and keep appropriate records. Such a scheme will require professional staffing from physicians and nurses to insure that the proper medical monitoring regime is followed. It will require a billing system to ensure that the members of the putative class are being reimbursed. These requirements are not very different from the requirements of setting up a medical practice like my own. Even for a practice like my own, which keeps track of and monitors a few hundred patients, the start-up costs alone are well in

excess of $75,000. For a program capable of monitoring thousands of patients, the start-up costs would be substantially higher.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on October 19, 2004

Merlin R. Wilson, M.D., F.A.C.P., F.A.C.R.